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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,533	03/08/2002	Alfred Jann	112843-035	5939
	7590	02/09/2004	EXAMINER	
Robert M Barrett Bell Boyd & Lloyd PO Box 1135 Chicago, IL 60690-1135			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/979,533

Applicant(s)

JANN ET AL.

Examiner

Irene Marx

Art Unit

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 7-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed 11/28/03 is acknowledged. Claims 6 and 23-24 are being considered on the merits.

Claims 1-5 and 7-21 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claim 24 of “further comprises a lipid source which “provides at least 50% of energy by monounsaturated fatty acids and less than 20% of energy by saturated fatty acids.” The recitation in the specification at page 4, paragraph 5 is:

“The lipid source is preferably rich in monounsaturated fatty acids; for example monounsaturated fatty acids may provide at least 50% of energy of the lipid source... Saturated fatty acids preferably provide less than 20% of the energy of the lipid source”.

This recitation differs substantially from the invention as claimed.

Therefore, this material constitutes new matter and should be deleted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Novak '873 or Toulmin '349 or Toulmin '799.

The claim is directed to a process of increasing insulin sensitivity in a mammal by the step of administering a composition comprising dextran, including dextran having a molecular weight above about 500,000.

Each of Novak '873 or Toulmin '349 or Toulmin '799 discloses a process of administering a composition comprising dextran to mammals having a molecular weight of about 500,000 or greater. The inherent result of this administration is an increase in insulin sensitivity in the mammal at least to some extent. See, e.g., Novak '873 (Col. 1, lines 51-70; Example 2) or Toulmin '349 (col. 2 and col. 4) or Toulmin '799 (col. 2, Examples I, II and IV).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the rejection over Novak '873 or Toulmin '349 or Toulmin '799 is inappropriate because the specification teaches a method of increasing insulin sensitivity based on the discovery that the colonic fermentation of dextran by microorganisms results in the production of relatively larger amounts of propionate as compared to non-digestible polysaccharides. Applicant concludes that the enteral administration of dextran provides a convenient and simple way of selectively increasing production of propionate which "can lead to an increase in insulin sensitivity".

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In response, it is noted that the as-filed specification does not appear to demonstrate that "selectively increasing production of propionate can lead to an increase in insulin sensitivity". Moreover, the claims are not directed to the enteral administration of dextran.

In response to Applicant's argument that the references do not disclose an increase in insulin sensitivity, a claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.

While discovery of the biological mechanism behind the administration of a known bioactive compound is clearly publishable in a peer-review journal, the criteria for patenting claims are distinct from publication criteria. For example, if the active step of the method is the same and the subject is the same, then the claimed method can be anticipated or made obvious by the prior art, even if the prior art does not recognize or appreciate this mechanism as long as the compound administered, dosage, mode of administration, subject, etc. are the same as in the method disclosed in the prior art.

If this were not so, one patent might issue with a one step claim of administering a compound to a subject in order to empirically treat a specific disease which is result of a contemporaneously unknown, disordered mechanism or pathway; and, then upon later discovery of the mechanism of the disorder, another patent could issue with a one step claim directed to the administration of the same compound to the same subject in order to modulate the specifically disordered mechanism or pathway. This would lead to multiple patents with essentially the same invention being patented, merely being couched in different words.

In *In re Cruciferous Sprout Litigation, Brassica_v_Sunrise.*, 64 USPQ2d 1202 (CA FC 2002), the Federal Circuit upheld a decision that patents owned by Johns Hopkins University and licensed to Brassica Protection Products, Inc. are invalid for anticipation by the prior art. The patents are for methods of growing and eating certain sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."

It is noted that all of the references discuss administration, in particular Toulmin '349 discusses the administration of dextran containing compositions at col. 4 and Toulmin '799 indicates that the puddings are smooth and palatable, which clearly indicates that they were administered prior to the date of instant invention (col. 4, lines 70 et seq.).

Therefore the rejection is deemed proper and it is adhered to.

Claims 6 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsuhashi *et al.* taken with Novak '873 or Toulmin '349 or Toulmin '799

Mitsuhashi *et al.* disclose a process of administering a composition comprising dextran to mammals for the purpose of promoting the growth of intestinal *Bifidobacterium*. A result of this administration is an increase in insulin sensitivity in the mammal at least to some extent (See, e.g., Examples 9 and 11 and page 5, lines 37-43), since it has as an effect the prevention of diabetes. In addition the reference discloses that the addition of certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides is beneficial to enhance the promotion of *Bifidobacterium* (See, e.g., Abstract), which further enhances the desired effect of increasing insulin sensitivity. The reference also discloses that the nutritional compositions containing dextran also comprise lipid sources in unsaturated fatty acids, such as unsaturated fatty acids *per se*. The reference is silent as to whether the lipid source provides at least 50% of energy by monounsaturated fatty acids, and less than 20% of energy by saturated fatty acids. ~~However~~, (See, e.g., page 3, lines 14-16).

The reference differs from the invention as claimed in that the molecular weight of the dextran used is less than about 500,000. However the reference discloses that the administration of compositions comprising dextran to mammals having a molecular weight of about 500,000 or greater as suitable for the claimed invention. See, e.g., page 3, lines 32-35.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Mitsuhashi *et al.* of administering compositions comprising dextran to mammals by using dextran of high molecular weight as disclosed in the reference, and by adding certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides and/or unsaturated fatty acids to the compositions for the expected benefits of providing a compositions which is more complete nutritionally and which has the

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effect of increasing the *Bifidobacterium* flora and of preventing diabetes by increasing insulin sensitivity at least to some extent.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant criticizes the Mitsuhashi reference as merely providing possible applications for dextran. However, it is apparent that this is precisely what applicant has done in the instant specification with respect to "an increase in insulin sensitivity". The data of record is directed to increases in propionic acid content in fecal sample. No data is provided directed to substantiate any increase in insulin sensitivity in a mammal by the claimed process. It is noted that the claimed invention is silent regarding the amount of dextran provided to achieve the desired effect of "increasing insulin sensitivity". As a matter of fact, the written disclosure does not set forth a protocol to measure and assess increases in insulin sensitivity in mammals.

Therefore, applicant's arguments fail to persuade and the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

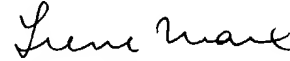
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 571-272-0919. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-9000.

A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx
Primary Examiner
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